K032020

SEP - 2 2003

510(k) Summary as required by 807.92

1. Company Identification

IIYAMA CORPORATION
710-1 Kitaowaribe, Nagano city, Nagano Pref. 381-0014, Japan
TEL: +81-26-263-5114
FAX: +81-26-263-5124

2. Official Correspondent

Kazuyoshi Tateiwa (Mr.) / Deputy Group Manager
Visual-Media Control Division
Technical Support Group
Technical No. 2 Dept.

3. Date of Submission

June 26, 2003

4. Device Trade name

51cm (20.1 inch) TFT Monochrome LCD Monitor, MU5111BW

5. Common Name

Monitor, display, workstation, and others

6. Classification

Medical displays were classified in Class II per 21 CFR 890.2050.

7. Predicate Device

Manufacturer	:	EIZO NANAO CORPORATION
Device Name	:	20.1" Monochrome LCD Monitor
Model Name	:	RadiForce G21
510(k) No.	:	K024358

8. Description of Device

51cm (20.1 inch) TFT Monochrome LCD Monitor, MU5111BW is a display for medical use.

9. Intended Use

51cm (20.1 inch) TFT Monochrome LCD Monitor, MU5111BW is intended to be used in displaying for diagnosis of X ray or MRI and others application for medical. This is the same intended use for the previously cleared for RadiForce G21, K024358.

10. Compliance standards

Please refer to Appendix 1.

Appendix 1: Comparison Table with Predicate Device

Items	G21	MU5111BW
510(k) Number	K024358	
Panel Size and Type	51 cm (20.1") TFT monochrome LCD panel	51cm(20.1") TFT monochrome LCD panel
Pixel Pitch	0.255 mm x 0.255 mm	0.255mm x 255mm
Available Cabinet Colors	Black	Black
Display Colors	1,531 grayscale tones	Maximum 256-level monochrome
Viewing Angles	H: 170°, V: 170°	H: 170°, V: 170°
Scanning Frequency (H, V)	Analog: 31.5 kHz – 130kHz, 50 kHz – 85kHz Digital: 31.5 kHz – 75kHz, 60 Hz (VGA Text: 70Hz)	f_H: 24.0-80.0kHz, f_V : 56-85Hz
Native Resolution	1600 x 1200 (landscape), 1200 x 1600 (portrait)	1600 x1200 (Landscape) 1200 x1600 (Portrait)
Brightness	700 cd/m²	700cd/m² (Typical)
Contrast Ratio	1000: 1 (Typical)	1000: 1 (Typical)
DOT Clock	Analog: 240MHz Digital: 162MHz	Digital: 162MHz
Response Time	30 ms (typical)	25ms
Input Signals	RGB Analog, DVI Standard 1.0	Analog: 0.7Vp-p(Standard), 75Ω Positive Digital: DVI Standard Rev.1.0
Input Terminals	DVI-D 29 pin, BNC	DVI-I 29pin
USB Ports / Standard	1 upstream, 2 downstream / Rev. 1.1	1upstream, 4downstream, Rev. 2.0/1.0
Serial Ports	D-Sub 9 pin (Remote Out), Min DIN 6 pin (Remote In) Mini DIN 8 pin (Photo Sensor)	Not provided.
Active Display Size (H, V)	408 mm x 306 mm (16.1" x 12.0")	408 mm x 306 mm (16.1" × 12.0")
Viewable Image Size	510 mm (20.1") (diagonal)	510mm (20.1") (diagonal)
Power Management	VESA DPMS DVI-DMPM	VESA DPMS
Power Consumption	55 watts (typical)	70 watts maximum
Power Save Mode	Less than 8 watts	Less than 5 watts
Dimensions (W x H x D)	With Stand: 449 mm x 456 – 528 mm x 209 mm (17.7" x 18.0" x 20.8" x 8.2") Without Stand: 449 mm x 347 mm x 86.5 mm (17.7" x 13.7" x 3.4")	466 x 424 – 534 x 241 mm / 18.3 × 16.7-21 × 9.5"
Luminance Calibration	Software (Standard) Photo-sensor (Standard) Protection panel (Standard)	No calibration software used. Auto adjustment function provided.
Power	10V-120V/200V-240V, 50/60Hz, 0.65A-0.4A, 0.35A-0.2A	100-230VAC, 50/60Hz 0.7-0.35A
NET Weight	With Stand: 10.5 kg (23.1 lbs), Without Stand: 7.3 kg (16.1lbs)	10kg / 22lbs
Certification & Standards	TUV/GM, c-TUV, CE, CB, EN60601-1, UL2601-1, CSA C22.2 No. 601-1, FCC-A, Canadian ICES-003-A, TUV/S, VCCI-A	Under applications for UL / C-UL, TUV-GS, CB, FCC-B and VCCI-B

- Comparing to a predicate device, EIZO NANAO RadiForce 21, Iiyama's MU5111BW has only a few differences. MU5111BW does not have serial ports, and automatic adjustment function provided. However, the basic structure of both models is the same in terms of LCD display with stand and its functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2003

Mr. Kazuyoshi Tateiwa
Deputy Group Manager
Iiyama Corporation
710-1 Kitaowaribe, Nagano City,
Nagano Pref., 381-0014
JAPAN

Re: K032020
Trade/Device Name: 51cm (20.1 inch) TFT Monochrome LCD Monitor, MU5111BW
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 27, 2003
Received: July 10, 2003

Dear Mr. Tateiwa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

June 26, 2003

INDICAITIONS FOR USE STATEMENT

510(k) Number (If known): K03 2020

Device Name: 51cm (20.1 inch) TFT Monochrome LCD Monitor, MU5111BW

Indications for Use:

51cm (20.1 inch) TFT Monochrome LCD Monitor, MU5111BW is intended to be used in displaying for diagnosis of X-ray or MRI, etc.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032020

Prescription Use √
(Per 21CFR 801.109)

OR

Over-The-Counter Use_____